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Fan-Gang Tseng

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02/24/2004

Bo-In Lin
13445 Mandoli Drive
Los Altos Hills, CA 94022

EXAMINER

GORDON, BRIAN R

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/892,014

Applicant(s)

TSENG ET AL.

Examiner

Brian R. Gordon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11-20-2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION***Election/Restrictions***

1. Newly submitted claims 11-20 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The method of claims 11 do not require that the method be performed by the apparatus of claim. While the method is directed manufacturing the apparatus, the apparatus is not required to be limited to being manufactured by the claimed method. The device may be manufactured from a different process such as first obtaining a block of cured silicone rubber and then etching or carving out material to produce the apparatus. Furthermore, claim 1 does not require that the device be manufactured in a photoresist layer.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 11-20 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments

2. Applicant's arguments with respect to claims 1-2 have been considered but are moot in view of the new ground(s) of rejection.

Claim Interpretations

Claim 2 has been amended to recite, "each of said micro-stamp sticks further comprising a micro-channel for holding a liquid sample of predefined volume provided for maintaining an air-liquid equilibrium specifically for said liquid sample held therein."

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The additional phrase does not further limit the structure of the micro-channel but provides for intentional use of the structure.

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

There is no significant structure limitation disclosed in the claim that reveals how this accomplishment. The examiner asserts that any device comprising a micro-channel would perform as claimed by applicant.

Claim Rejections - 35 USC § 112

3. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 recite cured silicon rubber, this appears to be improper for silicon is known to be a hard non-metallic element used in alloys and silicone rubber (the material that applicant appears to be using) is in fact a rubber made from silicone elastomers noted for its retention of flexibility.

Claim 5 is indefinite for there is no standard provided for one to determine what is a thickness of a photoresist layer. A photoresist layer can be any thickness desired by the manufacturer. Therefore the photoresist layer of the claim is being considered as any photoresist layer of any thickness. Furthermore, applicant is attempting to provide a structural limitation of the sticks in relationship to a photoresist layer that is not an element of the invention. If applicant intends to claim a specific thickness or thickness

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range, it should be clearly supported in the specification and claimed in a manner that specifies the thickness.

Claim 6 like claim 5 also attempts to limit the structure of the device by describing the elements of the invention in relationship to an unclaimed element (photoresist layer).

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Birch et. al. US 6,051,190.

Birch et al. disclose an apparatus for the transfer and dispensing small volumes of liquid, especially appropriate in the contexts of biological or chemical analyses and to a method for making the apparatus.

First, the material used to make the tool is mixed. In this particular embodiment, the material is a two component silicone rubber, which is intrinsically non-wettable due to its low surface tension, although any type of intrinsically non-wettable material could be used. In this particular example, the silicone rubber used is SYLGARD 184 from BASF which is mixed with a curing agent in the ration of 10 parts in weight of the curing agent for 100 parts of liquid polymer. Other examples of silicone rubber candidates include SYLGARD 182 from BASF or RTV 630 or 615 from General Electric Co.

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Next, the mold 30 for making the tool 20 is provided as illustrated in FIGS. 7 and 8A-8D. The mold 30 is a plate 32 with a plurality of holes 34 which extend through the plate from one surface 36 to the other opposing surface 38 of the plate 32. The diameter of each hole 34 is equal to the desired diameter of pins and the thickness of the plate 32 is equal to the required height of pins to prevent flooding of the rubber tool when the liquid is applied. The placement of the holes 34 in the mold 30 corresponds to the placement of the wells in the mini or micro-well plate. In this particular embodiment, the mold 30 is metallic although the mold 30 could be made out of other materials.

Next, one face 38 of the mold 30 is temporarily covered with a removable cover 40 as shown in FIG. 8B. In this particular embodiment, an adhesive tape is used to cover the holes 34 on one surface 38, although other materials to temporarily cover the holes 34 could be used.

Once the holes 34 on one face 38 of the plate 32 are blocked, then the material, in this particular example **silicone rubber**, is poured into the mold 30 as shown in FIG. 8C. The material is then allowed to set for a period of time at room temperature, typically ranging between 15 and 60 hours. In this particular embodiment, **the rubber is cured** at room temperature, e.g., at about 20 degrees C to 25.degrees C, overnight and is then post-cured at 100 degrees C for 1 hour. After the material is cured, the removable cover 40 is taken off the mold 30 which exposes the drop surface of the **rods or pins 18** for the tool 20 as shown in FIG. 8D. The removable cover 40 may also be removed before the rubber is post cured at 100.degrees C for 1 hour.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schurenberg et al. US 6,287,872 in view of Birch et al.

Schurenberg et al. disclose an invention that refers to sample support plates for the mass spectrometric analysis of large molecules, preferable biomolecules, methods for the manufacture of such sample support plates and methods for loading the sample support plates with samples of biomolecules from solutions together with matrix substance for the ionization of the biomolecules using matrix-assisted laser desorption (MALDI).

The droplets are applied in an efficient manner if the multiple pipette is located at a distance of 500 micrometers above the sample support. About 500 nanoliters of sample solution are pipetted from every pipette tip of the multiple pipette onto the sample support as shown schematically in FIG. 1. Usually the amount of sample solution in the pipette tip is sealed off by a gas bubble, therefore there is no more solution present in the channel (microchannel for holding a liquid sample) of the pipette tip afterward and the contact forces to the hydrophobic pipette tip are very minimal.

As seen in figure 1 the tapered pipette tips (of at least two different diameters and cross section) labeled as 4 are of the same length and comprise a channel for holding the liquid.

Schurenberg et al. does not disclose that the device is composed of silicone rubber.

Birch et al. disclose an apparatus for the transfer and dispensing small volumes of liquid, especially appropriate in the contexts of biological or chemical analyses and to a method for making the apparatus.

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First, the material used to make the tool is mixed. In this particular embodiment, the material is a two component silicone rubber, which is intrinsically non-wettable due to its low surface tension, although any type of intrinsically non-wettable material could be used. In this particular example, the silicone rubber used is SYLGARD 184 from BASF which is mixed with a curing agent in the ration of 10 parts in weight of the curing agent for 100 parts of liquid polymer. Other examples of silicone rubber candidates include SYLGARD 182 from BASF or RTV 630 or 615 from General Electric Co.

Next, the mold 30 for making the tool 20 is provided as illustrated in FIGS. 7 and 8A-8D. The mold 30 is a plate 32 with a plurality of holes 34 which extend through the plate from one surface 36 to the other opposing surface 38 of the plate 32. The diameter of each hole 34 is equal to the desired diameter of pins and the thickness of the plate 32 is equal to the required height of pins to prevent flooding of the rubber tool when the liquid is applied. The placement of the holes 34 in the mold 30 corresponds to the placement of the wells in the mini or micro-well plate. In this particular embodiment, the mold 30 is metallic although the mold 30 could be made out of other materials.

Next, one face 38 of the mold 30 is temporarily covered with a removable cover 40 as shown in FIG. 8B. In this particular embodiment, an adhesive tape is used to cover the holes 34 on one surface 38, although other materials to temporarily cover the holes 34 could be used.

Once the holes 34 on one face 38 of the plate 32 are blocked, then the material, in this particular example **silicone rubber**, is poured into the mold 30 as shown in FIG. 8C. The material is then allowed to set for a period of time at room temperature,

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typically ranging between 15 and 60 hours. In this particular embodiment, **the rubber is cured** at room temperature, e.g., at about 20 degrees C to 25.degrees C, overnight and is then post-cured at 100 degrees C for 1 hour. After the material is cured, the removable cover 40 is taken off the mold 30 which exposes the drop surface of the **rods or pins 18** for the tool 20 as shown in FIG. 8D. The removable cover 40 may also be removed before the rubber is post cured at 100.degrees C for 1 hour.

It would have been obvious to one of ordinary skill in the art at the time of the invention to manufacture the device of Schurenberg et al. by allowing the device to be manufactured from silicone cured in a mold as taught by Birch et al. that would allow for a channel to be formed to deposit matrices of biomolecules on a substrate for subsequent analysis.

6. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schurenberg et al. in view of Birch et al. as applied to claims 1-6 above, and further in view of Aoki US 6,326,212.

The modified teachings of Schurenberg do not disclose the device as having a plurality of micro-stamp tapered channels in fluid communication with one said micro-channel in each of said micro-stamp sticks.

Aoki discloses a dispensing apparatuses capable of simultaneously delivering fluid through an array of a plurality of pipettes (sticks).

As seen in figure 3 a plurality of spaced rows of concave depressions 42 are provided in bottom plate 39 (substrate). As seen in FIG. 4, each depression 42 has a central hole 43 (FIG. 6) and is aligned at its center or bottom area 44 (tapered) with an

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elongated needle or pipette 45 (sticks). Each pipette 45 is hollow (micro-channel in stamp sticks) and its interior opens into fluid contact with the interior of each depression 42 via holes 43.

It would have been obvious to one of ordinary skill in the art at the time of the invention to recognize that the modified teachings of Schurenberg et al. may be further modified by manufacturing the device to include a tapered micro-channel within the substrate by simply providing a mold of a corresponding shape as such that the tapering allows for sufficient and ease of fluid supply to each stick.

4. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schurenberg et al. in view of Birch et al. and Aoki as applied to claims 7-9 above, and further in view of Sunberg et al. US 6,451,188.

The modified teachings of Schurenberg do not teach a refilling means for refilling each of said plurality of micro-stamp tapered channels wherein said refilling means further comprising a refilling reservoir and a plurality of refilling micro-channels for refilling each of said plurality of micro-stamp tapered channels from said refilling reservoir.

Sunberg et al. disclose a system and apparatus in which fluid introduction is facilitated through the use of a port which extends entirely through a microfluidic substrate. Capillary forces can be used to retain the fluid within the port, and a series of samples or other fluids may be introduced through a single port by sequentially blowing the fluid out through the substrate and replacing the removed fluid with an alternate fluid, or by displacing the fluid in part with additional fluid.

As seen in figure 3 the structure of the microfluid substrate which allows access to the microfluidic channels introducing fluids and other materials. The device comprises a refilling means that is comprised of multiple refilling reservoirs and refilling micro channels connected with and supplying fluid to the ports 34.

Sunberg further discloses microfluidic analytical systems have a number of advantages over conventional chemical or physical laboratory techniques. For example, microfluidic systems are particularly well adapted for analyzing small sample sizes, typically making use of samples on the order of nanoliters and even picoliters. The substrates may be produced at relatively low cost, and the channels can be arranged to perform numerous specific analytical operations, including mixing, dispensing, valving, reactions, detections, electrophoresis, and the like. The analytical capabilities of microfluidic systems are generally enhanced by increasing the number and complexity of network channels, reaction chambers, and the like.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the modified teachings of Schurenberg et al. manufacturing the device to include the fluid supply system of Sunberg in order to provide a constant supply of fluid to the sticks and to dispense small samples on the order of nanoliters and picoliters.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Haslam et al., Gilbert, Gilbert et al., Vann et al., Garyantes, Pikarsky et al., and Yao disclose printing and liquid depositing devices.

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7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

brg


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